End Tidal Carbon Dioxide ($EtCO_2$)

ZOLL M Series

9650-0212-01 Rev. G

The issue date or revision level for this operation guide is shown on the front cover.
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END-TIDAL CARBON DIOXIDE ($EtCO_2$)

General Information

Product Description

The **M Series** End-Tidal Carbon Dioxide ($EtCO_2$) option continuously measures carbon dioxide and respiratory rate using a unique mainstream, solid-state infrared sensor called a Capnostat®. The Capnostat® sensor is attached to an airway adapter that connects to an endotracheal tube, similar airway, or disposable mouthpiece. Infrared light is generated by the sensor and beamed through the airway adapter to a detector on the opposite side of the airway. CO_2 (carbon dioxide), flowing through the airway adapter as a result of respiration, absorbs some of this infrared energy. The monitor determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by gases flowing through the airway. **End-Tidal Carbon Dioxide ($EtCO_2$)** is displayed as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a capnogram waveform may be displayed. This waveform is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube (ET) placement.

Respiration rate is calculated by measuring the time interval between detected peaks of the $EtCO_2$ capnogram waveform. The technology differentiates between waveforms caused by breathing and those caused by cardiogenic oscillations and artifact.

How to Use This Manual

This section explains how to set up and use the **M Series** End-Tidal Carbon Dioxide option. Important safety information relating to general use of the **M Series** End-Tidal Carbon Dioxide monitor appears in the “Safety Considerations” section of this manual.

The **M Series** Operator's Guide provides information operators need for the safe and effective use and care of the **M Series** products. It is important that persons using this device read and understand all the information contained within.

Please thoroughly read both safety considerations and warnings sections before operating your M Series product.

$EtCO_2$ Accessories

- Capnostat® CO_2 Sensor and Cable
- Sensor Cable Holding Clips, bag of 5
- SPU Pediatric/Adult Airway Adapter: Single patient use adaptor for ET tube sizes > 4.0 mm
- SPU Neonatal/Pediatric Airway Adapter: Single patient use adaptor for ET tube sizes ≤ 4.0 mm
- Reusable Adult Airway Adapter: Reusable adaptor for ET tube sizes > 4.0 mm
- Reusable Neonatal/Airway Adapter: Reusable adaptor for ET tube sizes ≤ 4.0 mm
- SPU Pediatric/Adult Airway Adapter with Mouthpiece: Single patient use adaptor and mouthpiece for non-intubated patients
- $Capno_2$ Mask Pediatric
- $Capno_2$ Mask Standard Adult
- $Capno_2$ Mask Large Adult

* Capnostat® is a registered trademark of Novametrix Corporation.

Safety Considerations

WARNINGS

General

- Before use, carefully read the **M Series** Operator's Guide, these operating instructions.
- The **M Series** $EtCO_2$ option is to be operated by qualified personnel only.
- The **M Series** $EtCO_2$ option should **NOT** be used as an apnea monitor.
- Do not immerse the **M Series** device, patient cables or sensors in water, solvents, or cleaning solutions.
- If the accuracy of any reading is suspect, first check the patient's vial signs by alternate means and then check the **M Series** $EtCO_2$ option for proper operation.
- If an alarm condition occurs while the alarms are suspended, the suspended alarm indications will only be visual displays and symbols.
- To ensure patient safety, the ECG-out jack and modem (if available) should only be connected to other equipment with galvanically isolated circuits.
- Elevated oxygen levels, nitrous oxide or halogenated agents contained in the breathing gases may degrade the accuracy of measurements made with the **M Series** $EtCO_2$ option. Oxygen compensation should be turned on if O_2 levels in excess of 60% are introduced. N_2O compensation should be used if nitrous oxide is introduced into the airway circuit. The presence of Desflurane beyond 5% may positively bias the carbon dioxide reading by up to 3 mmHg.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. Do not allow exposed portions of the patient's body to come in contact with metal objects, such as a bed frame, as unwanted pathways for defibrillation current may result.

Sensors and Airway Adapters

- Use only ZOLL / Novametrix Capnostat® sensor and airway adapters.
- The disposable Airway Adapters and disposable airway adapter with mouthpiece are intended for single patient use. Do NOT reuse or sterilize these disposable adapters, as system performance will be compromised.
- Inspect the sensor and airway adapter connections to ensure correct positioning.
- Do not use a damaged sensor or airway adapter.
- Do not sterilize or immerse the sensor.
- Do not place adult airway adapters between the ET tube and the breathing circuit elbow as this may allow patient secretions to block the adapter windows.
- Position airway adapters with windows in a vertical, NOT a horizontal, position. This helps keep patient secretions from "pooling" on the windows.
- To prevent moisture from draining into the airway adapter, do NOT place the adapter in a gravity dependent position.
- Always ensure the integrity of the patient breathing circuit after insertion of the airway adapter by verifying a proper CO_2 waveform (capnogram) on the monitor display.
- Do not apply tension to the sensor cable.
- Do not store sensors at temperatures less than -10° C or greater than 55° C.
- Do not operate sensors at temperatures less than 10° C or greater than 40° C.

All sensor and airway adapter questions with regards to the Declaration of Conformity with European Union Directives should be directed to the authorized representative for Novametrix:

Novametrix CE Contact
European Compliance Services, Ltd.
Oakdene House, Oak Road
Watchfield, Swindon Wilts
SN6 8TD, UK

Warranty (U.S. Only)

(a) ZOLL Medical Corporation warrants to the original equipment purchaser that beginning on the date of installation, or thirty (30) days after the date of shipment from ZOLL Medical Corporation's facility, whichever first occurs, the equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period of one (1) year. During such period ZOLL Medical Corporation will, at no charge to the customer, either repair or replace (at ZOLL Medical Corporation's sole option) any part of the equipment found by ZOLL Medical Corporation to be defective in material or workmanship. If ZOLL Medical Corporation's inspection detects no defects in material or workmanship, ZOLL Medical Corporation's regular service charges shall apply. (b) ZOLL Medical Corporation shall not be responsible for any equipment defect, the failure of the equipment to perform any function, or any other nonconformance of the equipment, caused by or attributable to: (i) any modification of the equipment by the customer, unless such modification is made with the prior written approval of ZOLL Medical Corporation; (ii) the use of the equipment with any associated or complementary equipment, (iii) installation or wiring of the equipment other than in accordance with ZOLL Medical Corporation's instructions. (c) This warranty does not cover items subject to normal wear and burnout during use, including but not limited to lamps, fuses, batteries, patient cables and accessories. (d) The foregoing warranty constitutes the exclusive remedy of the customer and the exclusive liability of ZOLL Medical Corporation for any breach of any warranty related to the equipment supplied hereunder. (e) Limitation of Liability: ZOLL shall not in any event be liable to Purchaser, nor shall Purchaser recover, for special, incidental or consequential damages resulting from any breach of warranty, failure of essential purpose, or under any other legal theory including but not limited to lost profits, lost savings, downtime, goodwill, damage to or replacement of equipment and property, even if ZOLL has been advised of the possibility of such damages.

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For additional information, please call ZOLL Medical Corporation at 1-800-348-9011. International customers should call the nearest authorized ZOLL Medical Corporation service center.

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$EtCO_2$ Indications for Use

The ZOLL **M Series** $EtCO_2$ option with Novametrix technology and Capnostat® sensor is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide ($EtCO_2$) and respiration rate in patients requiring ventilator support, transport, and anesthesia. The **M Series** $EtCO_2$ option is designed to monitor adult, pediatric, and neonatal patients.

The following substances can influence CO_2 measurements made with the Capnostat® Sensor: elevated oxygen levels, nitrous oxide, and halogenated agents. The **M Series** $EtCO_2$ option allows the user to enable high oxygen and/or nitrous oxide compensation. Halogenated anesthetic agents alter CO_2 readings but the M Series will monitor CO_2 within specifications when these agents are present at normal clinical levels. The presence of desflurane in the exhaled breath beyond normal values (5-6%) may positively bias measured Carbon Dioxide values by up to an additional 2-3 mmHg.

The **M Series** $EtCO_2$ option is intended for use only with the ZOLL / Novametrix Capnostat® sensor and airway adapters.

$EtCO_2$ Setup

The numeric $EtCO_2$ value is displayed in units of mmHg unless configured for percent or kPa. Refer to the *M Series Configuration Guide* (Part No. 9650-0201-01) for instructions on how to configure alternate units of measure.

Attach the Capnostat® sensor cable to the CO_2 connector at the back of the **M Series** product.

Turn the selector switch to **MONITOR** or **ON**.

Wait for the CO_2 sensor to warm up. The message "WARM UP" is displayed in the CO2 data field typically for less than one minute while the sensor warms to operating temperature. The message disappears when the sensor is ready for use.

Capnostat® SENSOR ZERO

The first time a particular Capnostat® sensor is connected to the monitor a "ZERO CO2 SENSOR" message will be displayed. Place the Capnostat® sensor on the "0" cell located on the sensor cable (see Figure 1).

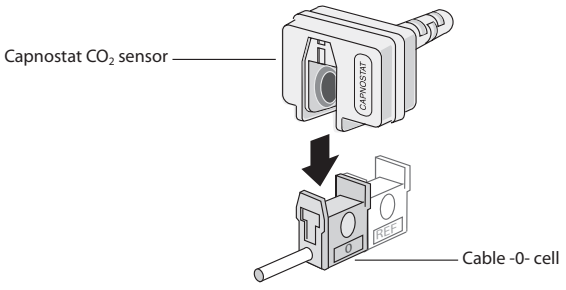


Figure 1

The sensor zero will be performed automatically and a "ZEROING CO2 SENSOR" message will be displayed typically for 15 seconds.

The **M Series** retains the sensor's zero calibration settings during and after its use. When a previously used sensor is reconnected to the **M Series**, sensor zeroing does not need to be repeated.

The sensor's calibration can be checked by placing the sensor on the "REF" cell for 5 or more seconds (see Figure 2).

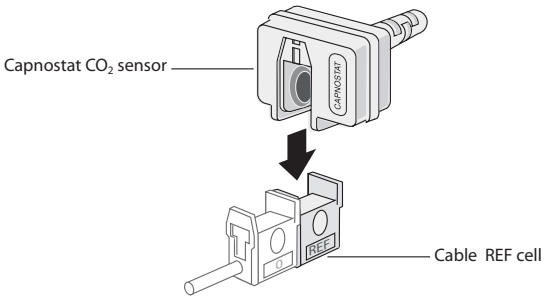


Figure 2

An $EtCO_2$ value of 38mmHg +/- 2 mmHg should be displayed.

WARNING

Removing the Capnostat® sensor from the "REF" cell before the 5 second calibration check period has elapsed will result in a need to rezero the sensor and the airway adaptor.

Attach the airway adapter to the Capnostat® sensor and perform an Airway Adapter zero if necessary.

Airway Adapter Zero

Adapter zeroing is required after switching between different airway adapter types.

Press the "**Param.**" softkey, select the "**EtCO2**" menu item, and then press "**Enter**".

Press the "**Zero**" softkey.

Place the sensor with the adapter installed away from all sources of CO_2 (including the patient's -- and your own -- exhaled breath and ventilator exhaust valves).

Select "**Start**" using the "**Zero**" softkey, then press "**Enter**".

"ZEROING CO2 ADAPTER" is displayed. The Airway Adapter zeroing process is typically finished within 15 seconds.

SELECTING AN AIRWAY ADAPTER

Select an airway adapter based on the patient's size, ET tube diameter and monitoring situation. For more information refer to the following table or contact ZOLL Medical Corporation.

Airway Adapter	Endotracheal Tube Diameter
SPU Pediatric/Adult	> 4.0 mm
Adult Reusable	> 4.0 mm
SPU Neonatal/Pediatric	≤ 4.0 mm
Neonatal Reusable	≤ 4.0 mm

DIRECTIONS FOR USE OF THE REUSABLE ADULT AND NEONATAL AIRWAY ADAPTERS

Reusable Adult Airway adapters should be used when monitoring intubated patients with Endotracheal Tube diameters greater than 4.0 mm. Reusable Neonatal Airway Adapters should be used when monitoring intubated patients with Endotracheal Tube diameters less than or equal to 4.0mm. Alternatively, disposable airway adapters may be used.

1. Verify that the airway adapter windows are clean and dry. Clean or replace the adapter if necessary.
2. Snap the airway adapter into the Capnostat® sensor. Align the arrow on the bottom of the airway adapter with the arrow on the bottom of the Capnostat®. Press the sensor and airway adapter together until they "click".
3. Perform an airway adapter zero (as described below) if switching between different airway adapter types. Press the "**Param.**" softkey and select the EtCO2 menu item then press "**Enter**". Place the sensor with the adapter installed away from all sources of CO_2 (including the patient's -- and your own -- exhaled breath and ventilator exhaust valves). Press the "**Zero**" softkey until the "**Start**" menu item is highlighted, then press "**Enter**". "ZEROING CO2 ADAPTER" will be displayed for approximately 15 seconds.
4. When using the Adult Airway Adapter, place the Capnostat® /Airway Adapter assembly at the proximal end of the airway circuit between the elbow and the ventilator circuit wye. Do not place the airway adapter between the ET tube and the elbow as this may allow patient secretions to block the adapter windows. Position the airway adapter with its windows in a vertical, NOT a horizontal, position. This helps keep patient secretions from "pooling" on the windows. If pooling does occur, the airway adapter may be removed from the circuit, rinsed with water and reinserted into the circuit. To prevent moisture from draining into the airway adapter, do NOT place the airway adapter in a gravity dependent position. See Figure 3.

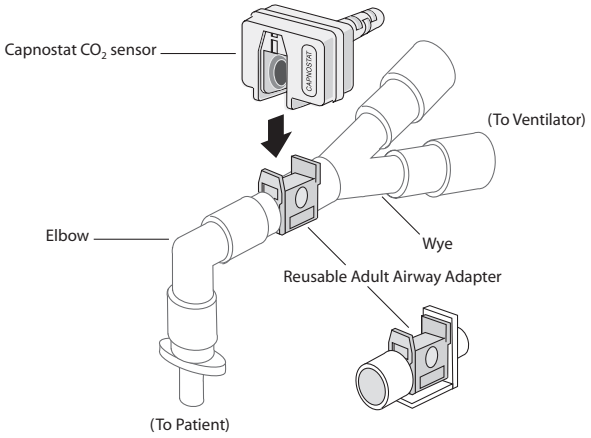


Figure 3

5. Check that connections have been made correctly by verifying the presence of a proper CO_2 waveform on the M Series display.
6. The sensor cable should face away from the patient. To secure the sensor cable safely out of the way, attach Sensor Cable Holding Clips to the airway tubing, then connect the sensor cable to the clips.

DIRECTIONS FOR USE OF THE SINGLE PATIENT USE PEDIATRIC/ADULT AIRWAY ADAPTER AND THE NEONATAL/PEDIATRIC AIRWAY ADAPTER

Disposable Pediatric/Adult Airway adapters should be used when monitoring intubated patients with Endotracheal Tube diameters greater than 4.0mm. Disposable Neonatal/Pediatric Airway Adapters should be used when monitoring intubated patients with Endotracheal Tube diameters less than or equal to 4.0mm. Alternatively, reusable airway adapters may be used.

Caution: The disposable Pediatric/Adult Airway Adapter is intended for single patient use. Do NOT reuse or sterilize the adapter as system performance will be compromised.

1. Remove adapter from the package. Verify the adapter is intact.
2. Snap the airway adapter into the Capnostat® sensor. Align the arrow on the bottom of the airway adapter with the arrow on the bottom of the Capnostat(. Press the sensor and airway adapter together until they "click".

3. Perform an airway adapter zero (as described below) if switching between different airway adapter types. Press the "**Param.**" softkey and select the EtCO2 menu item then press "**Enter**". Place the sensor with the adapter installed away from all sources of CO_2 (including the patient's -- and your own -- exhaled breath and ventilator exhaust valves). Press the "**Zero**" softkey until the "**Start**" menu item is highlighted, then press "**Enter**". "ZEROING CO2 ADAPTER" will be displayed for approximately 15 seconds.
4. When using the Neonatal/Pediatric Airway Adapter, place the Capnostat®/Airway Adapter assembly at the proximal end of the airway circuit between the endotracheal tube and the ventilator circuit wye. Position the airway adapter with its windows in a vertical, NOT a horizontal, position. This helps keep patient secretions from "pooling" on the windows. If pooling does occur, the airway adapter may be removed from the circuit, rinsed with water and reinserted into the circuit. To prevent moisture from draining into the airway adapter, do NOT place the airway adapter in a gravity dependent position (see Figure 4).

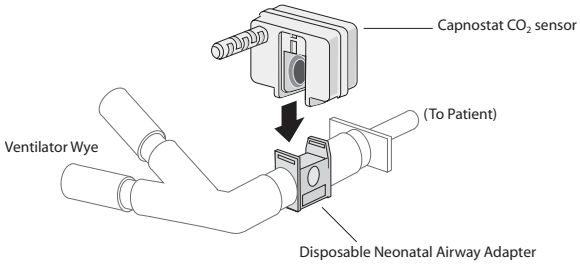


Figure 4

5. Check that connections have been made correctly by verifying the presence of a proper CO_2 waveform on the M Series display.
6. The sensor cable should face away from the patient. To secure the sensor cable safely out of the way, attach Sensor Cable Holding Clips to the airway tubing, then connect the sensor cable to the clips.

DIRECTIONS FOR USE OF THE SINGLE PATIENT USE PEDIATRIC/ADULT AIRWAY ADAPTER WITH MOUTHPIECE

The disposable Pediatric/Adult airway adapter with mouthpiece can be used for spot checking CO_2 on non-intubated adult or pediatric patients.

Caution: The disposable Pediatric/Adult Airway Adapter with mouthpiece is intended for single patient use. Do NOT reuse or sterilize the adapter, as system performance will be compromised.

1. Remove adapter with mouthpiece from the package. Verify that the adapter and mouthpiece are intact and securely fastened to each other.
2. Snap the airway adapter into the Capnostat® sensor. Align the arrow on the bottom of the airway adapter with the arrow on the bottom of the Capnostat®. Press the sensor and airway adapter together until they "click".
3. Perform an airway adapter zero (as described below) if switching between different airway adapter types. Press the "**Param.**" softkey and select the EtCO2 menu item then press "**Enter**". Place the sensor with the adapter installed away from all sources of CO_2 (including the patient's -- and your own -- exhaled breath and ventilator exhaust valves). Press the "**Zero**" softkey until the "**Start**" menu item is highlighted, then press "**Enter**". "ZEROING CO2 ADAPTER" will be displayed for approximately 15 seconds.
4. Patient should seal his or her mouth completely around the mouthpiece and breathe normally (see Figure 5).

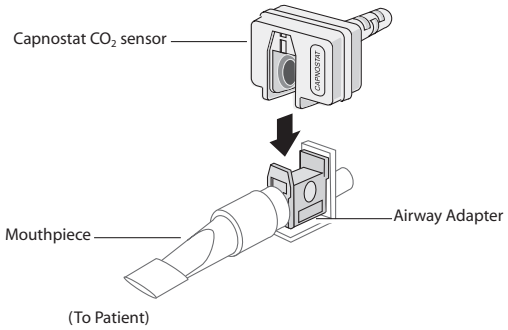


Figure 5

CLEANING SENSOR AND AIRWAY ADAPTERS

Cleaning the Capnostat® CO_2 Sensor

1. Clean the sensor surfaces with a damp cloth.
2. Ensure the sensor windows are clean and dry.
3. Do not immerse the Capnostat®.
4. Do not attempt to sterilize the Capnostat®.

Cleaning the Reusable Airway Adapters

1. The reusable Adult and Neonatal Airway Adapters may be cleaned by rinsing in a warm soapy solution, followed by soaking in a liquid disinfectant (refer to the disinfectant manufacturer's instructions for use). It should then be rinsed with sterile water and dried.
2. Before reusing the adapter, ensure the windows are dry and residue-free, and that the adapter has not been damaged during handling or by the cleaning process.

How $EtCO_2$ is Displayed

The **M Series** End-Tidal CO_2 option monitors both CO_2 and respiration rate. The results of this monitoring are displayed in the "CO2" field located in the upper left side of the **M Series** display. The **M Series** $EtCO_2$ option displays the maximum concentration of carbon dioxide detected during each breath. This maximum CO_2 concentration usually occurs at the end of expiration, thus the term "End Tidal CO_2" or $EtCO_2$. The numeric $EtCO_2$ value is displayed as "CO2 mmHg" if the units mmHg has been configured. Alternately the units of percent or kPa may be configured. Refer to the *M Series Configuration Guide* (Part No. 9650-0201-01) for instructions on how to configure alternate units of measure. The number of breaths per minute is displayed and labeled "RR" for respiration rate. In addition, a capnogram waveform may be selected using the "**Wave2**" softkey.

PHYSIOLOGICAL MONITORING

The physiological monitoring menu includes the following softkeys: "**Param**", "**Wave2**", "**ID#**, "**Alarms**", and "**12 Lead**."

"Param" Softkey

When the "**Param**" softkey is pressed, the following softkeys will be displayed: "**Select**", "**Enter"**, and "**Return**".

Pressing the "**Select**" softkey will scroll the highlighted area among the different available physiological parameters. Pressing the "**Enter**" softkey allows the user to select the parameter that is highlighted. Pressing the "**Return**" softkey allows the user to return to the physiological monitoring menu.

Selecting the $EtCO_2$2 parameter causes the following softkeys to appear: "**Zero**", "**Average**", "**Comp.**", "**Zoom**", and "**Return**". Note that the **Zoom** softkey is only displayed if the capnograph waveform is also displayed.

"Zero" Softkey

Adapter zeroing compensates for the optical differences between airway adapters and should be performed whenever the Airway adapter type has been changed. Adapter zeroing may also be necessary if the monitor displays "ZERO CO2 ADAPTER?".

Pressing the "**Zero**" softkey causes the start/cancel menu to appear. Pressing the "**Zero**" softkey again toggles the highlight between "**Start**" and "**Cancel**".

Pressing the "**Enter**" softkey with Start highlighted initiates zeroing of the adapter. The message "ZEROING CO2 ADAPTER" will be displayed during the zeroing process, which is typically finished in 15 seconds.

The "**Cancel**" selection halts the adapter zeroing process. Pressing "**Enter**" allows the user to enter the highlighted selection. Pressing "**Return**" will return the user to the $EtCO_2$ submenu.

"Average" Softkey

The **M Series** provides three (3) different time periods over which the highest $EtCO_2$ values are averaged: 1 breath, 10 seconds (default) and 20 seconds.

The user can select the averaging period by pressing the "**Average**" softkey. When the "**Average**" softkey is pressed the following softkeys will be displayed: "**Average**", "**Enter**", and "**Return**"

Pressing the "**Average**" softkey will scroll the highlighted area among the different averaging periods of 1 breath, 10 seconds and 20 seconds.

Pressing the "**Enter**" softkey allows the user to select the highlighted averaging period. Pressing the "**Return**" softkey returns the user to the $EtCO_2$ submenu. Pressing the "**Return**" softkey again will return the user to the physiological monitoring menu.

"Comp" Softkey

The **M Series** provides the ability to compensate for elevated levels of oxygen and/or the presence of nitrous oxide. Oxygen compensation should be activated when oxygen levels in excess of 60% are present in the airway circuit. Nitrous oxide compensation should be activated when nitrous oxide is present in the airway circuit.

If the concentration of oxygen in the breathing circuit exceeds 60% and nitrous oxide is in use, both O_2 and N_2O should be activated.

When the "**Comp**" softkey is pressed, the following softkeys will be displayed: "**Comp.**", "**Enter**", and "**Return**".

Pressing the **Comp.** softkey will scroll the highlight among the different types of compensation available (either NONE, O2, N2O, or O2 & N2O). The "O2&N2O" selection turns oxygen and nitrous oxide compensation on. Two asterisks (*), located on the left side of the CO2 field, will be displayed indicating compensation for both oxygen and nitrous oxide. The left asterisk indicates oxygen compensation is active and the right asterisk indicates nitrous oxide compensation is active. The "O2" selection turns oxygen compensation on and displays an asterisk in the far left of the CO2 field. The "N2O" selection turns nitrous oxide compensation on and displays an asterisk to the right of the O2 asterisk. The "NONE" selection will turn all compensations off and eliminate the asterisks from the display. After selecting the appropriate compensation press "**Enter**" to activate the selected function.

Pressing the "**Return**" softkey will return the user to the $EtCO_2$ submenu. Pressing the "**Return**" softkey again will return the user to the physiological monitoring menu.

"Zoom" Softkey

The user can select the zoom level for capnogram waveforms by pressing the "**Zoom**" softkey. When the "**Zoom**" softkey is pressed the scale for the displayed capnogram waveform will scroll among 0-12.5 mmHg, 0-25 mmHg, 0-50 mmHg, 0-75 mmHg, and 0-100 mmHg.

The scales are 0-1.7, 0-3.3, 0-6.6, 0-10, and 0-13.3 if units of kPa or % have been configured. (Refer to the*M Series Configuration Guide* for instructions on how to configure alternate units of measure.)

Displaying the Capnogram "Waveform"

M Series systems allow the user to display one or two waveforms when in the Monitor, Defib, or Manual (AED) mode. Only one waveform will be displayed in Pacer mode.

Pressing the "**Wave2**" softkey from the physiological monitoring menu cycles the display from the capnogram waveform, to the plethysmograph waveform (if SpO_2 is installed), to no second waveform displayed.

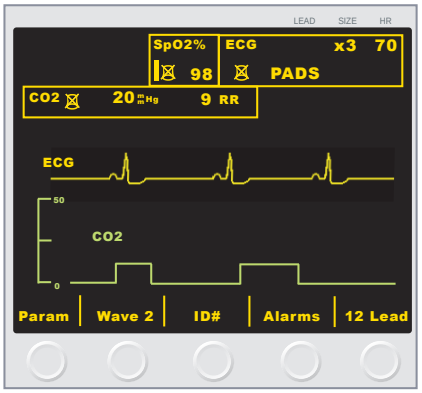
A second waveform can be displayed provided that the defibrillator is not charging or an ECG analysis is not in progress. The waveform will be temporarily removed from the display, if currently visible, when any of the following buttons is pressed: **Charge**, **Analyze**, **Energy Select**, **Sync On/Off**.

The second waveform will be restored to the display under the following conditions:

- 3 seconds after a shock is delivered
- 3 seconds after an analysis is completed, unless the defibrillator is charging
- 4 seconds after the last **Energy Select** button press
- 3 seconds after Sync mode is turned off

The Capnogram waveform is displayed at half the speed of the ECG display, and provides 8 seconds of data.

Use the "**Zoom**" softkey from the $EtCO_2$ submenu to adjust the waveform display size. Numbers shown on the left side of the Capnogram display indicate the scaling.



Recorder Operation

To start the strip chart recorder, press the **RECORDER** button. The recorder will run continuously until the button is pressed again.

Each time the strip chart recorder is started, the time, date, ECG lead, size, heart rate, respiration rate, and $EtCO_2$ value are printed on the top part of the paper. If selected, the Capnogram waveform will also be printed with the selected scaling under the ECG trace.

All waveforms printed by the recorder are delayed by six seconds relative to their occurrence.

Alarms

The **M Series** $EtCO_2$ option provides user programmable "out of range" alarms for both End Tidal CO_2 and Respiration Rate. Press the "**Alarms**" softkey to display the Alarm Set screen and softkeys.

The $EtCO_2$ and respiration rate alarms share the same State field and cannot be enabled or disabled separately. Enabling the $EtCO_2$ alarms enables both $EtCO_2$ and respiration rate alarm functions. Disabling $EtCO_2$ or respiration rate alarms disables the other alarm function.

Press the **Inc** or **Dec** softkeys to select "ENABLE", "DISABLE", or "AUTO" for both the $EtCO_2$ alarm and the respiration rate alarm. Pressing the **Next Field** softkey when either "ENABLE or "DISABLE" has been chosen will set the selected State for $EtCO_2$ and respiration rate and move the highlight to the next field (Low limit field).

When "AUTO" has been selected for $EtCO_2$ and respiration rate and the **Next Field** softkey is pressed, the unit will automatically set the lower and upper limits for $EtCO_2$ and respiration rate. For $EtCO_2$, the limits will be set to +/- 25% of the patient's currently measured $EtCO_2$ value. If the $EtCO_2$ value is greater than 40 mmHg (which is equivalent to 5.3kPa or 5.3% at a barometric pressure of 760 mmHg), then 10 mmHg (1.3 for kPa or %) will be added and subtracted from the reading to set the upper and lower limits. The auto alarm limits are set only if valid measurements are present for the vital sign.

For the automatic respiration rate alarm limits, the unit will set the lower and upper limits for respiration by adding and subtracting the values shown in the following table from the patient's current breath rate.

Respiration Limits		
Respiration Rate Average	**High Limit**	**Low Limit**
1-15 breaths/min.	+7 breaths/min.	-50% value
16-40 breaths/min.	+10 breaths/min.	-7 breaths/min.
> 40 breaths/min.	+15 breaths/min.	-10 breaths/min.

Refer to the “Alarms” section of the *M Series Operator’s Guide* for further details.

The **M Series** device has three levels of alarms.

1. **High Priority**: If enabled, these alarms reflect physiological parameters that are outside the previously set limits. They will cause a continuous audio tone, highlight the alarming parameter and flash the associated alarm bell.
2. **Medium Priority**: These alerts reflect equipment related user correctable faults such as “LEAD OFF” and “ZERO CO2 ADAPTER”. They will cause a two beep audio tone and display a message for a timed period.
3. **Low Priority**: These are informational messages to the user, such as WARMUP, and will have no audio indication.

Alarm Limits

The following table shows the low and high alarm limit ranges for $EtCO_2$ and default values.

EtCO2 Alarm Limit Ranges			
	mmHg	**%**	**kPa**
Low Alarm Limit Range	0 to 95	0 to 12.5	0 to 12.6
Low Alarm Limit Default	25	3.2	3.3
High Alarm Limit Range	5 to 100	0.6 to 13.1	0.6 to 13.3
High Alarm Limit Default	55	7.2	7.3

The Low respiration rate Alarm Limit range is 0 to 100 respirations per minute with default setting of 5. The High respiration rate Alarm Limit range is 5 to 150 respirations per minute with a default setting of 120.

Suspending Alarms

When a high priority alarm occurs, a continuous audible tone will sound, the value of the alarming parameter will be highlighted and the bell associated with that parameter will flash.

Press the **ALARM SUSPEND** button to silence the alarm. An “X” will be placed through the flashing bell ( ) to indicate that alarms associated with the affected parameter have been audibly disabled. The value of the alarming parameter remains highlighted. Pressing the **ALARM SUSPEND** button again or correcting the alarm violation will reactivate the alarm processing.

If a second alarm occurs while the first alarm is suspended, press the **ALARM SUSPEND** button to suspend the second alarm tone.

Activating / Deactivating Alarms

Pressing and holding the **ALARM SUSPEND** button for approximately 3 seconds will deactivate alarm functions. All bells will have an "X" through them) to indicate that alarms are deactivated.

If all alarms are deactivated and the **ALARM SUSPEND** button is briefly pressed, all of the enabled alarm functions will be activated. (Refer to the “Setting Alarms” section of the *M Series Operator’s Guide*).

Automated External Defibrillator (AED) Operation

M Series AED's equipped with End Tidal Carbon Dioxide operate in a slightly different way than Manual and Advisory models equipped with $EtCO_2$. These differences are explained below.

Semi-Automatic Operation

The capnogram waveform cannot be displayed in Semi-Automatic mode.

Although $EtCO_2$ alarm functions are operational in semi-automatic mode, Heart Rate alarm functions are disabled. Background ECG analysis functions, however, continue to operate as described in the "AED" section of the *M Series Operator's Guide*.

The $EtCO_2$ monitoring parameters can be changed by pressing the "**Param**" softkey.

The **ALARM SUSPEND** button can be used to activate, deactivate, or audibly disable the $EtCO_2$ alarms as described previously. The alarm limit settings cannot, however, be changed in semi-automatic mode; only the default alarm limits are available. See the *M Series Configuration Guide* for information on setting alarm limit defaults.

Manual Mode Operation

The capnograph waveform can be displayed by pressing the "**Wave2**" softkey, provided that the defibrillator is not charging or an ECG analysis is not in progress. The waveform will be temporarily removed from the display, if currently visible, when any of the following buttons are pressed: **CHARGE**, **ANALYZE**, **ENERGY SELECT**, **SYNC ON/OFF**. The second waveform will be restored to the display under the following conditions:

- 3 seconds after a shock is delivered
- 3 seconds after an analysis is completed, unless the defibrillator is charging
- 4 seconds after the last **ENERGY SELECT** button press
- 3 seconds after Sync mode is turned off

The waveform cannot be displayed in pace mode.

Both Heart Rate and $EtCO_2$ alarms are operational. The alarm limits can be changed by pressing the "Alarms" softkey. The $EtCO_2$ monitoring parameters can be changed by pressing the "**Param**" softkey.

Check Out Procedure

The following procedure verifies that the sensor has been zeroed correctly, and that the alarms are functional:

1. Attach the Capnostat® sensor cable to the rear of the **M Series** product.
2. Turn the selector switch to **MONITOR** mode or **ON** (for AED models select "**Manual Mode**").
3. Connect sensor to "0" cell, which is located on the Capnostat® sensor cable.
4. Wait for the CO_2 sensor to warm up and zero (if required). The message "WARM UP" is displayed typically for less than one minute. If sensor zero is required, the message "ZEROING CO2 SENSOR" displays.
5. After warm-up and zeroing is complete, connect the sensor to the "REF" cell, located on the Capnostat® sensor cable, for at least 5 seconds.
6. Verify that the displayed CO_2 value is 38mmHg +/- 2 mmHg.
7. Press the "Wave2" softkey. Verify that the capnogram waveform appears as a straight line at approximately 38mmHg.
8. Verify that the patient alarms are functional by entering the alarm menu, selecting enable, and setting the low $EtCO_2$ alarm limit to 45. Press "**Return**" and then **ALARM SUSPEND**. Verify that the alarm tone is issued, the alarming parameter's value is highlighted, and the alarm bell flashes on the display. Repeat with the $EtCO_2$ low alarm set at 30 and the high alarm set at 35.
9. Remove the sensor from the reference cell and verify that "CHECK CO2 ADAPTER" appears in the message area of the graphic display and a two beep audio tone sounds.

When not in use, place Capnostat® sensor on the zero cell.

DEFAULT SETTINGS

When the $EtCO_2$ option is turned on, the following default settings are automatically selected and remain in operation until changed.

Parameter	Default Setting	Range
High $EtCO_2$ Alarm Limit	55 mmHg	5 to 100 mmHg, OFF
Low $EtCO_2$ Alarm Limit	25 mmHg	0 to 95 mmHg, OFF
High Respiration Rate Alarm Limit	120 respirations per minute	5 to 150 respirations per minute, OFF
Low Respiration Rate Alarm Limit	5 respirations per minute	0 to 100 respirations per minute, OFF
Averaging Mode	10 seconds	1 breath 10 seconds 20 seconds

Note: The power on default settings for the capnogram waveform scale and CO_2 compensation are set in System Configuration, as are the power-on default settings for alarm limits. See the *M Series Configuration Guide* for more information.

MESSAGES AND TROUBLESHOOTING

The following chart lists the messages that may appear on the **M Series** unit relating to $EtCO_2$, possible causes, and the action(s) to take if the message indicates a problem.

The operator should become thoroughly familiar with this information before monitoring patients.

Message	**Possible Cause(s)**	**Recommended Action(s)**
CHECK CO2 SENSOR	Sensor cable not properly plugged in or over temperature.	Check that sensor cable is plugged and seated properly. Check sensor is not exposed to excessive heat. If problem persists, replace sensor.
CO2 OUT OF RANGE Dashed lines for CO2	Calculated CO_2 value is greater than 100 mmHg	Gas mixture is beyond the maximum range of the sensor.
WARM UP	Sensor is warming up. This takes up to 5 minutes.	Wait for sensor to warm up (max 5 minutes).
REPLACE CO2 SENSOR	When "WARM UP' message is displayed for more than 5 minutes, this message will be displayed. Sensor is defective or incompatible.	Replace sensor.
ZERO CO2 ADAPTER? alternating with CHECK CO2 ADAPTER	Airway adapter removed, occluded, or Adapter Zeroing needs to be performed or was performed incorrectly -- for example, if CO_2 was present in the adapter during zeroing.	Replace/clean airway adapter. Check/perform adapter zero.
ZERO CO2 SENSOR alternating with PLACE ON ZERO CELL	Sensor cable plugged into M Series for the first time. Zeroing error or probe drift error detected.	Place sensor on the zero cell. Zeroing performed automatically.
ZEROING CO2 SENSOR	Sensor zeroing in progress. This is started when the sensor is placed on the zero cell.	Wait for sensor zeroing to finish.
USE ROOM AIR ADAPTER	Adapter zeroing started with CO_2 in the adapter, or the adapter is on the "REF" or "0" cell.	Place CO_2 sensor on adapter in room air.
ZEROING CO2 ADAPTER	Adapter zeroing in progress.	Wait for adapter zeroing to finish.
CO2 COMM ERROR	No or invalid communication from the $EtCO_2$ module.	Return for service.
CO2 UNIT ERROR	Defective $EtCO_2$ module.	Return for service.
Dash lines at top of waveform capnogram.	Scale value setting incorrect. Measured CO_2 higher than scale limits.	Adjust to higher scale setting.
CO2 numeric value displays as dash lines.	After a defibrillation discharge, the numeric value will display "----" for approximately 10 seconds.	None, normal operation.

SPECIFICATIONS

Principle of Operation	Non-Dispersive Infrared (NDIR) absorption, dual wavelength ratiometric-True Single Beam Optics. Complies with conditions on BTPS (Body Temperature and Pressure, Saturated): EtCO2 = partial pressure of CO_2 in the expiratory gas.
Sensor Type	Mainstream
Warmup Time	Operational in 15 seconds, full specification within 60 seconds.
Rise Time	< 60 mS adult and ≤ 50 mS neonate
Delay Time	< 35 mS adult and ≤ 25 mS neonate
System Response Time	< 95 mS adult and ≤ 75 mS neonate
End Tidal CO_2 ($ETCO_2$) Range	0 - 100 mmHg
End Tidal CO_2 ($ETCO_2$) Accuracy	0 - 40 mmHg ±2 mmHg, 41 - 70 mmHg ±5%, 71 - 100 mmHg ±8%
End Tidal CO_2 ($ETCO_2$) Resolution	1 mmHg
End Tidal CO_2 ($ETCO_2$) Stability	±2 mmHg or ±5% of reading (whichever is greater), 1 - 100 mmHg over 8 hours without re-zero
Respiration Rate (RR) Range and Accuracy	0 - 150 respirations per minute (averaged over the last 8 breaths) ±1 resp/min.
Respiration Rate (RR) Resolution	1 breath/min.
$ETCO_2$ Alarm Limits	User selectable, High: 5 to 100 mmHg, Low: 0 to 95 mmHg, OFF
Respiration Rate (RR) Alarm Limits	User selectable, High: 5 to 150 respirations per minute, Low: 0 to 100 respirations per minute, OFF
$ETCO_2$ Alarm Accuracy	0 - 40 mmHg ±2 mmHg, 41 - 70 mmHg ±5%, 71 - 100 mmHg ±8%
O_2/N_2O Compensation	User selectable
Halogenated Agents	Specification allows for halogenated anesthetic agents that may be present at normal clinical levels. The presence of desflurane in the exhaled breath beyond normal values (5-6%) may positively bias Carbon Dioxide values by up to an additional 2-3 mmHg.
Barometric Pressure Compensation Range	550 - 780 mmHg (automatic)
Airway Adapter Deadspace	Adult < 5cc, Neonatal < 0.5cc
Environmental	Operating Temperature: 10º to 40º C Storage and Shipping Temperature: -10º to 55º C The **M Series** device may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use.
Electromagnetic Immunity ($EtCO_2$ Option)	AAMI DF-2: IEC 1000-4-3 to 15 V/m
Software Hazards	Minimized by compliance with EN1441
Operating Time ($EtCO_2$ and SpO_2 Options)	For a new, fully charged battery pack at 20°C: 35 defibrillator discharges at maximum energy (360J), or 1.5 hours minimum of continuous ECG monitoring, or 1.0 hour of continuous ECG monitoring/pacing at 60 mA, 70 beats/min.

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